MAR 2 8 2000

K000495

Appendix F
Attachment 1.0
Summary Statement

BALLARD
MEDICAL PRODUCTS®
12050 Lone Peak Parkway
Draper, Utah 84020
(801) 572-6800
Fax: (801) 572-6999

510(k) Premarket Notification Summary Statement

Ballard Medical Products® Epidural and Spinal Needles

Thursday, February 10, 2000

Submitter Information per 807.92(a)(1):

Mark L. Bussone, Director of Regulatory Affairs and Quality Assurance
Ballard Medical Products
12050 Lone Peak Parkway
Draper, UT., 84020
Tel. (770) 587-8393
Fax. (770) 587-7762

Proprietary Name per 807.92(a)(2):

Ballard Medical Products® Epidural and Spinal Needles

Common Name per 807.92(a)(2):

Epidural and Spinal Needles

Classification per 807.92(a)(2):

The Ballard Medical Products® Epidural and Spinal Needles have been classified as Class II device(s) through the Anesthesiology Panel per 21 CFR 868.5150. Classification Name is: Needle, Conduction, Anesthetic (with or without introducer). Product Code: BSP

Legally marketed equivalent(s) per 807.92(a)(3):

The Ballard Medical Products® Epidural and Spinal Needles device(s) are substantially equivalent to the ISPG Lancet Spinal, Spinal with Notch, and Epidural Needles - #K962886; Sherwood Medical Lancet Spinal Needle - #K822630; Sherwood Medical Spinal Needle with Notch - #K951312; and B. Braun Medical Epidural Needle - #K813236.

Description of the device 807.92(a)(4):

The needles presented in this 510(k) Premarket Notification application are equivalent to other anesthesia needles on the market that have been approved for marketing through the Premarket Notification process. This is a "me-too" device. The subject device(s) has the same technological characteristics as legally marketed predicate devices. Specifically, the features, specifications, materials, and mode of action are equivalent.

Intended Use per 807.92(a)(5):

The Ballard Medical Products® Epidural and Spinal Needles are intended to be used for those patients requiring the injection of anesthetic agents through 1) the epidural space, 2) entry into the spinal cavity.

BALLARD
MEDICAL PRODUCTS®
12050 Lone Peak Parkway
Draper, Utah 84020
(801) 572-6800
Fax: (801) 572-6999

Technological Characteristics (equivalence to predicate devices) per 807.92(a)(6):

The Ballard Medical Products® Epidural and Spinal Needles general design characteristics and functionality are similar in that they meet performance standards where applicable for:

Stainless Steel components: ISO 9626
Hub: ISO 594 1/2
Hub to Needle Bond Strength: ISO 7864
Color: ISO 6009

Determination of Substantial Equivalence (non-clinical data) per 807.92(b)(1):

The following in vitro tests were performed on the proposed Ballard Medical Products® Epidural and Spinal Needles:

a) First Article Inspection:

Dimensional Criteria, Conformance to Standards.

Conclusions from non-clinical data per 807.92(b)(3):

Based on the indications for use, technological characteristics, and performance testing, the Ballard Medical Products® Epidural and Spinal Needles have shown to be safe and effective for their intended use(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2000

Mr. Mark L. Bussone
Ballard Medical Products
12050 Lone Peak Parkway
Draper, UT 84020

Re: K000495
Ballard Medical Products® Epidural and Spinal Needles
Regulatory Class: II (two)
Product Code: 73 BSP
Dated: February 10, 2000
Received: February 15, 2000

Dear Mr. Bussone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon for

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000495

Device Name: **Ballard Medical Products® Epidural and Spinal Needles**

Indications for Use:

Epidural Needles: Used to introduce anesthetic agents to the epidural space.

Spinal Needles: Used to achieve entry into the spinal cavity for the delivery of anesthetics.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____

Joann S. Weitershaus

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000495